

## **PATIENTS AND CONSUMERS COALITION**

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September 15, 2000

Jane E. Henney, M.D.  
Commissioner, Food and Drug Administration  
14-71 Parklawn Building, 5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner Henney:

As representatives of very diverse consumer and patient advocacy organizations, we write in response to the FDA's request for comments regarding the *Prescription Drug Users Fee Act* (PDUFA) passed in 1993 and reauthorized by Congress (PDUFA II) when it passed the FDA Modernization Act (FDAMA) in 1997. The request for comment is detailed in the Federal Register notice (Docket No. 00N-1364).

This letter concentrates on questions one and two of the Federal Register notice, regarding the serious concerns that the undersigned organizations have about the overall structure and intent of PDUFA, as well as with the "performance goals" established within the Act. Many of our organizations will provide detailed testimony on questions three and four, which deal with how user fees should or should not be used, at the FDA's public meeting on September 15<sup>th</sup>.

**1. PDUFA creates a financial dependence by the FDA on an industry it regulates. This is a conflict-of-interest that could compromise drug safety.** Our organizations recognize that PDUFA has provided the agency with the resources to speed up new drug approvals since 1993. In fact the approval time has been cut in half from approximately 23 months in 1993 to 12 months in 1998. Clearly there are public health benefits to be gained from faster approval of certain new drugs. These include medications that treat serious and life-threatening conditions, drugs that provide relief for patients with illness or disability refractory to existing therapies, or drugs that are less toxic than currently available therapies.

However, the FDA's direct fiscal interest in optimizing user fee income to achieve speedier approval times and get more drugs through the approval process in each budget year creates an obvious tension with its responsibility to assure the highest degree of safety and efficacy of new products. The integrity of the drug approval process is what is potentially at risk and, as a result, the safety of the millions of Americans who use prescription drugs could be compromised.

**The growing number of recalls and warnings related to newly approved drugs has reinforced our concerns.** The agency has attempted to demonstrate that there is no relationship between faster approval times and more frequent recalls or additional safety warnings. However, there have been too many recent withdrawals of marketed drugs that have killed and maimed

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people that have cast a serious shadow over the integrity of the approval process. This worrisome trend appears to be continuing, as evidenced by the recent withdrawals of Propulsid, Rezulin and the decision to mandate a first-ever Medication Guide for Lotronex (alosetron.)

As the FDA's analysis presented in the Federal Register Notice shows, its dependency on fees paid by the regulated industry has grown dramatically since fees were first initiated in 1993. This growth is projected to continue through 2002, when the FDA estimates that user fees will provide half of the \$325 million dollars allocated to carry out the agency's statutory responsibility to assure the safety and efficacy of new drugs.

As if to confirm our fears, the term "customer" has crept into the FDA's characterization of the prescription drug industry. We are very concerned that an agency chartered to safeguard the public's health would characterize the industry it regulates as its primary customer, and itself as a "supplier" of services (namely new drug review and approval.) It is the public, not the drug industry, that should be the FDA's "customer." The medical and public health consequences of faster drug approval are the appropriate measure of PDUFA's successes and failures, not the tabulation of the average number of months a drug requires for approval.

Moreover, it appears that the user fee program is draining resources from other areas of the FDA with critically important public health responsibilities (e.g., adverse event monitoring, generic drug reviews, etc.) thus distorting the overall priorities of the agency.

**2. PDUFA's performance goals are inappropriate, potentially dangerous and open to manipulation by the drug industry.** Although the FDA takes pains to explain that the performance goals mandated under PDUFA are for decision-making, not approval, these goals put the FDA under tremendous financial pressure to move very quickly on the overall approval process. These goals force the agency to take a "one size fits all" approach to drug approvals. It may not be in the public interest to require the FDA to act at the same speed for all standard or priority drugs and biologics. Some should get more time, some should receive less; time should not be the measurement of the agency's success. The agency has adequate tools to enable patients to obtain drugs before they are approved for marketing (as with the Treatment IND), so that desperately ill patients can have early access to potentially important medicines.

Moreover, it is completely inappropriate to give a regulated industry a dominant voice in determining what will be the process ("performance goals") for oversight of that industry. Congress established these goals in consultation with the prescription drug industry and received absolutely no input from consumers. The end result is that the regulated industry controls not only the funding and timeline for new drug approval, but the measurement tools that are used to determine the FDA's success or failure in this matter.

Finally, PDUFA allows companies to manipulate the FDA into quickly approving drugs that the agency has not had adequate time to review. Companies can do this simply by dragging their feet in submitting required data and test results until the FDA's "performance" deadline draws closer. If this practice is used on a regular basis, it puts the FDA under tremendous time pressure to meet its performance goals without adequately reviewing the submitted data. In other words,

the FDA's performance goals, which are based on the agency's ability to meet many decision-making deadlines over the course of time, may actually provide companies with an incentive to delay transmitting some data to the FDA quickly. If they give the FDA the information "too early," the agency might actually have more time to find flaws in the information.

**3. PDUFA does not prioritize between speedy approval of drugs that are truly important and those that represent no therapeutic advancement.** Unfortunately, the FDA's regulatory process as defined by statute and regulation does not provide it the latitude to prioritize the new drug approval process based on a ranking of medical and public health needs. We suggest that a drug for erectile dysfunction, or the third or fourth cox-2 inhibitor, does not need to be rushed to market as quickly as an important new anti-cancer agent or an enzyme replacement therapy for a genetic disease. Many new drugs that have appeared on the market as a result of the agency's PDUFA enhanced approval resources, may actually turn out to provide little, if any, benefit to patients when compared to older, better-understood and often less expensive predecessor drugs.

**4. The best way to insure the timely approval of safe drugs is to adequately fund the FDA from general revenues.** Adherence to this principle would be the surest way to remove the worrisome potential for conflict-of-interest that arises when dedicated income streams flow to the regulator from the regulated industry. If Congress continues to refuse to adequately fund the FDA, it will be essential for Congress and the agency to establish better procedures and guidelines to prevent the serious conflict-of-interest concerns that our organizations have raised in this letter.

For more information, please contact Travis Plunkett with the Consumer Federation of America at (202) 387-6121.

Sincerely,

Center for Medical Consumers  
Consumer Federation of America  
National Consumers League  
National Organization for Rare Disorders  
National Women's Health Network  
UAW--United Automobile, Aerospace and Agricultural Implement Workers of America